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EXAMINER
FORMAN, BETTY J

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/911,047	ERIKSON ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-9 and 12-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 6-9 12-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 25 August 2004 in which claims 1, 12, 13, 24, 25 and 27 were amended, claims 5, 10 and 11 were canceled and a Declaration under 35 U.S.C. § 1.131 was submitted. The Declaration and amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action dated 9 April 2004, not reiterated below are withdrawn in view of the amendments and/or Declaration. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection, necessitated by amendment, are discussed.

Claims 1-4, 6-9 and 12-29 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-4, 6, 8, 17-18, 20, 22, 24-25, 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Kukreti et al (Nucleic Acids Research, 1997, 25(21): 4264-4270).

Regarding Claim 1, Kukreti et al disclose the method of assaying sequence-specific hybridization comprising combining a biopolymer target and biopolymer probe to provide a test sample, applying a first stimulus (spectrophotometer illumination) to the test sample, detecting a first signal from the test sample (spectrophotometer detection), applying a second stimulus (spectrophotometer illumination) to the test sample, detecting a second signal from the test sample(spectrophotometer detection) and comparing the first and second signals to accomplish the assaying wherein at least one label is provided in the sample (page 4265, left column, second full paragraph "oligonucleotides") and first and second stimulus and first and second signals are photonic (page 4265, left column, last paragraph-right column first and second paragraphs) and wherein the method comprises an intermediate electronic stimulus (i.e. electronically applied heat via Haake PG20). Kukreit et al teach their method of sequence-specific hybridization via melting analysis wherein every 8 minutes the sample is stimulated and detected via the spectrophometer during the heating from 0° C to 80° C using the Haake PG20 thermoprogrammer as illustrated in Fig. 2. Hence, they stimulate and detect using electromagnetic radiation with intermediate electronic stimulus as claimed.

Regarding Claim 2, Kukreit et al disclose the method wherein the first stimulus is photonic (spectrophotometer illumination) and the second stimulus is electronic (i.e. electronically applied heat via Haake PG20).

Regarding Claim 3, Kukreit et al disclose the method wherein the first and second stimulus is photonic (spectrophotometer illumination) (page 4265, left column, last paragraph-right column first and second paragraphs).

Regarding Claim 4, Kukreit et al disclose the method wherein the first stimulus is electronic (i.e. electronically applied heat via Haake PG20) and the second stimulus is photonic (spectrophotometer illumination).

Regarding Claim 5, Kukreit et al disclose the method wherein the first and second stimuli are electronic (i.e. electronically applied heat via Haake PG20).

Regarding Claim 6, Kukreit et al disclose the method wherein application of first and second stimuli is at least "partially coextensive" i.e. the electronically applied heat is continuously applied (page 4265, left column, last paragraph-right column first paragraph).

Regarding Claim 8, Kukreit et al disclose the method wherein the first and second signals are photonic (page 4265, left column, last paragraph-right column, first paragraph).

Regarding Claim 11, Kukreit et al disclose the method wherein the electromagnetic radiation is photonic (page 4265, left column, last paragraph-right column, first paragraph).

Regarding Claim 17, Kukreit et al disclose the method wherein the probe and target contain nucleobases and hybridize to form a duplex i.e. the triplex of Kukreit comprises a duplex (page 4265, left column, last paragraph-right column, first paragraph and Fig. 2).

Regarding Claim 18, Kukreit et al disclose the method wherein the probe and target contain nucleobases and hybridize to form a triplex (page 4265, left column, last paragraph-right column, first paragraph and Fig. 2).

Regarding Claim 20, Kukreit et al disclose the method wherein the probe is a nucleic acid analog comprising a cationic moiety (page 4265, Fig. 1).

Regarding Claim 22, Kukreit et al disclose the method further comprising applying at least one additional stimulus, detecting at least one additional signal and comparing the first, second and additional signals to accomplish the assaying i.e. the signal is detected every eight minutes during application of heat (page 4265, left column, last paragraph-right column, first paragraph and Fig. 2).

Regarding Claim 24, as stated above, the claim is indefinite for the recitation "signal is applied". For purposes of examination, the claim is interpreted as "signal is detected". This interpretation properly depends from Claims 1 and 22 wherein the signals are detected. Kukreit et al detect a signal every 8 minutes thereby detecting the first and second signals non-continuously by (page 4265, left column, last paragraph-right column, first paragraph and Fig. 2).

Regarding Claim 25, as stated above, the claim is indefinite for the recitation "signal is applied". For purposes of examination, the claim is interpreted as "signal is detected". This interpretation properly depends from Claim 1 wherein the signals are detected. Kukreit et al detect a signal every 8 minutes thereby detecting the first and second signals non-continuously by (page 4265, left column, last paragraph-right column, first paragraph and Fig. 2).

Regarding Claim 27, Kukreti et al disclose the method of assaying sequence-specific hybridization comprising adding a biopolymer target and biopolymer probe to a binding medium to provide a test sample (i.e. hybridization buffer, page 4265, right column, lines 6-13), applying a first stimulus (spectrophotometer illumination) to the test sample, detecting a first signal from the test sample (spectrophotometer detection), applying a second stimulus (spectrophotometer illumination) to the test sample, detecting a second signal from the test sample(spectrophotometer detection) and comparing the first and second signals to accomplish the assaying wherein at least one label is provided in the sample (page 4265, left column, second full paragraph "oligonucleotides") and first and second stimulus and first and second signals are electromagnetic (page 4265, left column, last paragraph-right column first and second paragraphs) and wherein the method comprises an intermediate electronic stimulus (i.e. electronically applied heat via Haake PG20). Kukreit et al teach their method of sequence-specific hybridization via melting analysis wherein every 8 minutes the sample is stimulated and detected via the spectrophometer during the heating from 0° C to 80° C using the Haake PG20 thermoprogrammer as illustrated in Fig. 2. Hence, they stimulate and detect using electromagnetic radiation with intermediate electronic stimulus as claimed.

Response to Arguments

4. Applicant argues that "one of ordinary skill in the art would not interpret "applying an electronic stimulus to a test sample" to encompass electrical heating of a water bath in which a container containing the test sample is immersed." While, Applicant has not provided any support for this assertion, the assertion is not found convincing because as Applicant

acknowledges, Kukreti et al apply an electronic stimulus to the water bath (page 9, lines 13-14 of the response). Because the sample is in the water bath and because an electronic stimulus is applied to the water bath, an electronic stimulus is applied to the sample via the water bath. Applicant appears to be asserting that the claims require a direct electrical contact between the sample and a source of electricity (e.g. a nucleic acid immobilized on an electrode or applying voltage directly to the sample). However, the claims are not so limited. The claims merely require "an electronic stimulus". As applicant acknowledges, an electronic stimulus is applied. Hence, the reference teaches the claimed stimulus.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 7, 9, 12-16, 19, 21, 23, 26, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kukreti et al (Nucleic Acids Research, 1997, 25(21): 4264-4270) in view of Meade et al (U.S. Patent No. 6,071,699, issued 6 June 2000).

Regarding Claims 7, 9, 12-16, 19, 21, 23, 26, 28 and 29, Kukreti et al disclose the method of assaying sequence-specific hybridization comprising combining a biopolymer target and biopolymer probe to provide a test sample, applying a first stimulus (spectrophotometer illumination) to the test sample, detecting a first signal from the test sample (spectrophotometer detection), applying a second stimulus (spectrophotometer illumination) to

the test sample, detecting a second signal from the test sample(spectrophotometer detection) and comparing the first and second signals to accomplish the assaying wherein at least one label is provided in the sample (page 4265, left column, second full paragraph "oligonucleotides") and first and second stimulus and first and second signals are photonic (page 4265, left column, last paragraph-right column first and second paragraphs) and wherein the method comprises an intermediate electronic stimulus (i.e. electronically applied heat via Haake PG20). Kukreit et al teach their method of sequence-specific hybridization via melting analysis wherein every 8 minutes the sample is stimulated and detected via the spectrophometer during the heating from 0° C to 80° C using the Haake PG20 thermoprogrammer as illustrated in Fig. 2. Hence, they stimulate and detect using photonic means with intermediate electronic stimulus as claimed.

Meade et al teach photonic stimuli is electronic (i.e. electromagnetic radiation inducing electron transfer, Column 24, lines 1-3) and they teach stimulation and detection via differing combinations of light and/or electronics (Column 35-67) and as such they teach the first and/or second stimuli and detection of Kukreit is electronic or photonic as claimed. Meade et al teaches an embodiment wherein the electronic stimulus is voltage (Column 24, lines 41-43); wherein energy is transferred to generate a signal (Column 24, lines 41-67); wherein at least one label chemiluminescent or electrochemiluminescent (Column 23, lines 61-63); wherein at least one label is an electron spin label (Column 23, line 50); wherein the probe and target bind to form a quadruplex (e.g. target, probes and label Fig. 2); wherein at least the probe or target contains an amino acid sequence (i.e. PNA, Column 6, lines 60-67); wherein the probe or target is bounded to a substrate (Column 8, lines 50-64); wherein the probe or target is a peptide (i.e. PNA, Column 6, lines 60-67); and wherein the probe is not a biopolymer i.e. electron transfer moiety (Column 7, lines 21-35). Meade et al further provides motivation to use their labeling system wherein they teach greatly enhanced signal-to-noise results wherein pulsed

initiation (i.e. repeated stimuli) provides two to four orders of magnitude improvement in signal-to-noise (Column 27, lines 39-50).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the labels and detection of Meade et al to the signal detection of Kukreit et al for the expected benefits of obtaining two to four orders of magnitude improvement in signal-to-noise as taught by Meade et al (Column 27, lines 39-50).

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
October 22, 2004